

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Effects of Licorice on Relief and Recurrence of Menopausal Hot Flashes

#### Protocol summary

##### Summary

The aim of the present study is to assess the effects of Licorice on relief and recurrence of menopausal hot flashes in postmenopausal women referring to healthcare centers affiliated to Shahid Beheshti Medical University. A total of 90 postmenopausal women were randomly assigned into intervention or control group to receive either 330mg capsules of Licorice or 330mg capsules of starch powder, 3 times a day for 8 weeks. The frequency and severity of hot flashes measure and compare between the two groups (At the end of each week, for 2 weeks before the intervention, for 8 weeks of the intervention for 4 weeks of followed up stage).

#### General information

##### Acronym

Hot Flashes

##### IRCT registration information

IRCT registration number: **IRCT201103264317N3**

Registration date: **2011-05-15, 1390/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-15, 1390/02/25

##### Registrant information

###### Name

Fatemeh Nahidi

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 982188202512

###### Email address

nahidi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

The Pharmaceutical Sciences Research Center of Shahid Beheshti Medical Sciences University providing facilities and funding source to conduct this study.

##### Expected recruitment start date

2009-03-20, 1387/12/30

##### Expected recruitment end date

2009-12-21, 1388/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Licorice on Relief and Recurrence of Menopausal Hot Flashes

##### Public title

Effects of Licorice on Relief and Recurrence of Menopausal Hot Flashes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The subjects were between 45-60, had body mass index (BMI) under 29, experienced amenorrhea at least 1 year or at most 3 years, suffered from hot flash and used no drug or hormone to relieve it. In addition, they had no known disease in their medical records, didn't take antidepressants or sedatives, were married or lost their husbands not sooner than 1 year, experienced no stressful event (e.g. death of close family members, divorce etc.) in the past 6 months, were not vegetarian or had no allergy to herbs as well as no history of estrogenic cancers in themselves or their close relatives. Exclusion criteria: The subjects were decided to use drug or hormone and herbals medicin to relieve hot flashes.

##### Age

From **45 years** old to **60 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **90**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Single

#### **Other design features**

Age, duration of amenorrhea as well as onset, frequency and severity of hot flash as intervening variables were matched

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Shaheed Beheshti University of Medical Sciences and Health Services

##### **Street address**

Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital, Evin, Tabnak St., Shaheed Chamran Avenue, Tehran, Iran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2010-01-21, 1388/11/01

#### **Ethics committee reference number**

5538-114-03-86

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Hot flash

#### **ICD-10 code**

N95.1

#### **ICD-10 code description**

Menopausal and female climacteric states

## **Primary outcomes**

### **1**

#### **Description**

Relief

#### **Timepoint**

Weekly

#### **Method of measurement**

Information form

### **2**

#### **Description**

Recurrence

#### **Timepoint**

Weekly

#### **Method of measurement**

Information form

### **3**

#### **Description**

Frequency of hot flash

#### **Timepoint**

At the end of each week, for 2 weeks before the intervention , for 8 weeks of the intervention for 4 weeks of followed up stage

#### **Method of measurement**

Information form

### **4**

#### **Description**

Severity of hot flash

#### **Timepoint**

At the end of each week, for 2 weeks before the intervention , for 8 weeks of the intervention for 4 weeks of followed up stage

#### **Method of measurement**

Information form

## **Secondary outcomes**

### **1**

#### **Description**

Daily food intake

#### **Timepoint**

At the end of each week

#### **Method of measurement**

Information form

### **2**

#### **Description**

Blood pressure

#### **Timepoint**

Weekly

#### **Method of measurement**

Sphygmomanometer( instrument for measuring blood pressure)

### 3

**Description**

Weight

**Timepoint**

Weekly

**Method of measurement**

Scale

## Intervention groups

### 1

**Description**

Licorice capsules contained 330mg licorice root abstract. The subjects took them for 8 weeks 3 times a day (morning, noon and night).

**Category**

Treatment - Drugs

### 2

**Description**

Placebo capsules had 330mg starch with the same shape. The subjects in control group took them for 8 weeks 3 times a day (morning, noon and night).

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Health care centers affiliated to Shahid Beheshti Medical University .

**Full name of responsible person**

Fatemeh Nahidi faculty member of Shaheed Beheshti University of Medical Sciences ,MSc in Midwifery a

**Street address**

Health care centers affiliated to Shahid Beheshti Medical

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Sbmu Pharmaceutical Sciences Research Center

**Full name of responsible person**

Farshad H. Shirazi

**Street address**

Sbmu Pharmaceutical Sciences Research Center ,School of Medicien, Below of Niyayesh,Avenue Valiasr

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sbmu Pharmaceutical Sciences Research Center

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Shaheed Beheshti University of Medical Sciences and Health Services

**Full name of responsible person**

Fatemeh Nahidi

**Position**

Faculty member of Shaheed Beheshti University of Medical Sciences ,MSc in Midwifery and student of P

**Other areas of specialty/work****Street address**

Women's affairs Office, Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital, Evin, Tabnak St., Shaheed Chamran Avenue, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 2243 9912

**Fax****Email**

nahidifateme@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shaheed Beheshti University of Medical Sciences

**Full name of responsible person**

Fatemeh Nahidi

**Position**

MSc in Midwifery and student of PhD in Health Education

**Other areas of specialty/work****Street address**

Women's affairs Office, Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital, Evin, Tabnak St., Shaheed Chamran Avenue, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 4421 8052

**Fax****Email**

nahidifateme@yahoo.com , nahidi@sbmu.ac.ir

**Web page address**

Chamran Avenue, Tehran, Iran

**City**

Tehran

**Postal code****Phone****Fax****Email****Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shaheed Beheshti University of Medical Sciences

**Full name of responsible person**

Fatemeh Nahidi

**Position**Faculty member ,MSc in Midwifery and student of PhD  
in Health Education**Other areas of specialty/work****Street address**Women's affairs Office, Shaheed Beheshti University  
of Medical Sciences and Health Services, Beside  
Taleghani Hospital, Evin, Tabnak St., Shaheed**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*